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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,604	02/27/2002	Minas Theodore Coroneo	29264/38278	4164

4743 7590 03/01/2005

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,604	CORONEO, MINAS THEODORE	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 10-22* is/are pending in the application.

4a) Of the above claim(s) *13 and 15-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,10-12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's Amendment filed October 21, 2004 and Response to a Notice of a Non-Compliant Amendment filed December 13, 2004 are acknowledged.

In the last Office Action the subject matter under consideration were those methods and compositions comprising Gadolinium for the treatment of glaucoma, claims 3 and 10-14. Those methods and compositions comprising other compounds, claims 15-22, were withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions.

An Information Disclosure Statement filed October 18, 2002 was further acknowledged. None of the references therein cited was present in the parent file. Those references have been supplied by Applicant and reviewed by the Examiner.

The objection to the disclosure set forth in the last Office Action is withdrawn. The word "protect" has been inserted in claim 3, line 4, between "to" and "retinal".

Newly amended, and now independent, claim 13 is presently directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Originally, claim 13 was dependent from independent claim 12, a composition claim. Claim 13 has been amended such that it now is drawn to a "device".

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 13 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because the present claims are drawn to the treatment of glaucoma and an eye drop solution. Correction is required. See MPEP § 608.01(b).

Upon reconsideration the rejection of claims 3 and 10-14 under judicially created doctrine as being drawn to an improper Markush group is withdrawn.

In the last Office Action claims 3 and 10-14 were rejected under 35 U.S.C. 112, first paragraph, as lacking a clear written description of the invention and of the manner and process of practicing it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the same, and, not setting forth the best mode contemplated by the inventor to carry out the invention.

Subsequent to the deletion of the recitation "other pressure sensitive mechanisms of retinal ganglion cells", this rejection of record is withdrawn.

Claims 3 and 10-14 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention in the last Office Action. The claims are directed to the treatment of glaucoma and compositions in the formulation of an eye drop solution. The specification provides neither support for the administration of Gadolinium for treatment of glaucoma nor support for compositions comprising Gadolinium as an eye drop or systemic preparation. It was asserted the instant

specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation.

Applicant argues at pages 8-10 of the specification, there is a description of how to make formulations containing stretch-activated channel blocking agents such that one skilled in the art would be guided by this description to formulate compositions for the treatment of glaucoma. Further, Applicant urges potency values may be readily calculated and topical absorption across ocular membranes can be readily tested.

It is noted page 10 of the specification is the first page of the claims. The discussion on pages 8-9 is a general one that is silent with respect to ocular solutions comprising Gadolinium and the use of Gadolinium in the treatment of glaucoma.

Applicant's arguments have been given careful consideration but are not found persuasive. The rejection of record is repeated for the reasons of record over claims 3, 10-12 and 14. As a rare earth element, one skilled in the ophthalmology art would not readily consider Gadolinium as a safe and effective agent for use in the treatment of glaucoma, in particular, by way of an eye drop or systemic administration. The activity of Gd+3 is complex and most likely has multiple mechanisms and sites of action depending upon its concentration. On the contrary, some specific guidelines, or motivation to select Gadolinium would reasonably be required by those skilled in the art.

The art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

Claim 12 was rejected under 35 U.S.C. 102(b) in the last Office Action as being anticipated by Calabrese et al., European Journal of Neuroscience. It was asserted Calabrese teaches a composition comprising Gadolinium with one or more excipients.

This rejection is withdrawn because there is no motivation to prepare an ophthalmic solution in view of Calabrese.

No claim is allowed.

Hamill et al. Pharmacological Reviews, pages 237-240, is cited to show further the state of the art. See, in particular, the first column on page 239.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

February 26, 2005